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REC'D 02 JUN 2004
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

07 SEP 2004

Applicant's or agent's file reference 80360 WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/00411	International filing date *(day/month/year)* 16.01.2003	Priority date *(day/month/year)* 04.03.2002
International Patent Classification (IPC) or both national classification and IPC A61K7/16, A61K7/16		
Applicant SOCIETE DES PRODUITS NESTLE S.A. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.09.2003	01.06.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Menidjel, R Telephone No. +31 70 340-3680

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/00411

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-11 received on 31.03.2004 with letter of 31.03.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-11
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 - The following documents (D1,D2) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:
D1: US-A-5 853 704 (GAFFAR ABDUL ET AL) 29 December 1998 (1998-12-29)
D2: EP-A-0 575 121 (ROHM & HAAS) 22 December 1993 (1993-12-22)

- The amendments filed by the applicant do not introduce subject-matter which extends beyond the content of the application as filed (Article 34(2)(b) PCT).

2. Clarity/Remarks (Article 6 PCT)

a - Present claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, namely "...an agent that chemically blocks functional groups in cGMP" which merely amounts to a statement of the underlying solution, without providing the technical features necessary for achieving this result.

- As far as the claimed subject-matter can be understood in view of the unclarity mentioned above, the following is to be noted concerning novelty and inventive step:

3. Novelty (Article 33(2) PCT)

- The subject-matter of present claims 1-11 is new for the following reasons (Article 33(2) PCT):
- Document D1 describes an aqueous composition of caseino-glycomacropeptide (cGMP) exhibiting a reduced off-flavour by reducing the pH of the composition below 7.0. The composition comprises also an agent that can chemically blocks functional groups in cGMP , i.e. maleic anhydride acid (Cf. D1, column 2, lines 25-67; column 3, lines 6-22; column 3, line 48-column 4, line 8; column 4, lines 43-67).
The difference between the subject-matter of present claim 1 and the teaching of document D1 is that the cGMP containing aqueous composition does not comprise the incorporation of a hydrophobic resin.

- Document D2 refers to the treatment of food products and by-products, i.e. milk products and by-products to remove therefrom off-flavours by treating them with an absorbent resin

such as Amberlite XAD (Cf. D2, page 2, lines 38-58; page 3, lines 13-18; page 3, lines 32-49; page 4, lines 28-32).
Document D2 describes the possibility to regenerate the absorbent resin by the use of acidic regenerants, basic regenerants, oxidising regenerants or elevated temperatures. It is not mentioned within document D2 if one the cited acidic regenerants or oxidising regenerants can chemically block functional groups in cGMP (Cf. D2, page 4, lines 33-44). Therefore, the difference between the subject-matter of present claim 1 and the teaching of document D2 is that the aqueous composition does not comprise an agent that chemically blocks functional groups in CGMP.

4. Inventive Step (Article 33(1),(3) PCT)
a - The subject-matter of present claims 1-11 is considered inventive for the following reasons (Article 33(1),(3) PCT):

- The subjective problem to be solved by the present application is to provide a cGMP containing aqueous composition which does not develop an off-flavour during long storage (see application on page 2, lines 8-9 and lines 17-19).

- The solution accorded to the present claim 1 consists in a cGMP containing aqueous composition comprising a hydrophobic resin and an agent that chemically blocks functional groups in cGMP; and optionally, the pH of the composition is below about 7.

- Document D2, which is considered as the closest prior art, refers to the treatment of food products and by-products, i.e. milk products and by-products to remove therefrom off-flavours by treating them with an absorbent resin such as Amberlite XAD (Cf. D2, page 2, lines 38-58; page 3, lines 13-18; page 3, lines 32-49; page 4, lines 28-32).

- The claimed subject-matter differs from the teaching of the prior art D2 in the presence of an agent that chemically blocks functional groups in cGMP; and optionally, the pH of the composition is below about 7.

- The technical effect of this difference is that the composition provides an increased stability and a reduced off-flavour formation, when exposed to room-temperature (see application as filed, on page 3, lines 15-18).

Neither D2,D1 nor their combination renders the subject-matter of present claims 1-11

obvious. Therefore, the subject-matter of present claims 1-11 involves an inventive step (Article 33(1),(3) PCT).

5. Industrial Application (Article 33(4) PCT)

- The subject-matter of present claims 1-11 is considered to be industrially applicable; claims 1-11 therefore, satisfy the criterion set forth in Article 33(4) PCT.

Claims

1. A cGMP containing aqueous composition exhibiting a reduced off-flavor even after long storage, comprising
   (i) a hydrophobic resin; and
   (ii) an agent, that chemically blocks functional groups in cGMP;
   and optionally,
   (iii) the pH of the composition is below about 7.

2. The composition according to claim 1, wherein the hydrophobic resin is selected from the group consisting of Serdolith III, Lewatit EP-63, Lewatit OC 1064, Lewatit OC 1066, Lewatit VC-OC or Amberlite XAD.

3. The composition according to claim 1 or 2, wherein the blocking or masking agent is selected from the group consisting of succinic anhydride, maleic anhydride, propio-lactone, chlorophillin or derivatives thereof.

4. The composition according to any of the preceding claims, wherein the pH of the final product is in the range of from about 3 to about 7.

5. The composition according to any of the preceding claims, wherein the amount of the hydrophobic resin is in the range of from 0.01 to about 5 wt.-%, preferably from 0.05 to about 5 wt.-%, more preferably from 0.1 to about 2 wt.-%,, each based on the final product.

6. The composition according to any of the preceding claims, wherein the amount of the blocking agent is in the range of from 0.005 to 1 wt.-%, preferably 0.01 to 1 wt.-%, more preferably 0.01 to 0.6 wt.-%, more preferably 0.1 to 0.5 wt.-%, each based on the final product.

Claims

7. The composition according to any of the preceding claims, which is an aqueous formulation having a water activity value between 0.2-1, preferably between 0.7-0.9 and more preferably of about 0.8.

8. The composition according to any of the preceding claims, which is a food product, a pharmaceutical product, a cosmetic or an oral composition.

9. The composition according to claim 4 or 7, which is a product for oral hygiene, a tooth paste, a gel, a tooth powder, a mouth wash, a chewing gum, a tablet or a lozenge.

10. A method of producing a composition according to any of the claims 8 or 9, which comprises:
preparing a composition comprising cGMP,
adding an agent chemically blocking functional groups in cGMP and a hydrophobic resin, and/or
adjusting the pH to a value in the range of from about 3 to about 7.

11. Use of a composition according to any of the claims 1 to 7 in the manufacture of a medicament or a composition for treating or preventing caries, plaque formation, dental diseases, diseases of the mouth cavity or gums.